SEP 13 2011

K102483

510(k) Summary for the Bacterial/Viral HME Filter (BHF 104)

Name and Address of Sponsor

Sunset Healthcare Solutions, Inc
2201 S. Halsted St.
Suite 1344
Chicago, IL 60608

Name and Address of Manufacturer

Altera Tibbi Malzeme San Ve Tic As.
Turan Mah Tire Organize Sanayi
Bolgesi,Tire/Izmir
Aegean Region, 35900
Turkey
Phone: 90-232-2375949

Establishment Registration Number

3006534321

Name and Address of Official Correspondent

Regulatory Insight, Inc.
5401 S. Cottonwood Ct.
Greenwood Village, Colorado 80121
Contact: Mr. Kevin Walls, RAC
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Date Summary was Prepared

December 17, 2010

Device Name

Trade Name: Bacterial/Viral HME Filter (BHF 104)
Common Name: Disposable Heat and Moisture Exchanger and Bacteria/Viral Filter
Classification Name: Breathing circuit bacterial filter

Classification, Panel and Product Code

Class 2, Anesthesiology,
Regulation Number: 868.5260
Product Code: CAH

Indications for Use

The BHF 104 is a disposable single-use filter for patients who require humidification during the delivery of ventilator gases and provide filtration for reducing possible cross-contamination between patient and equipment. The BHF 104 is for use in hospital, ICU, anesthesia, and respiratory therapy.

Legally Marketed Device to Which Substantial Equivalence is Claimed

DATEX-OHMEDA HMEF 500 (K021265)

Device Description

The BHF 104 filter is a single-use, barrier type filter, fabricated from a plastic resin, and delivered to the customer in a sealed, non-sterile package. The translucent housing has aligned connector ports (15mm ID x 22mm OD, 22mm ID x 15mm OD), a perpendicular filter media, and a gas sampler luer port, protruding at 45 degrees from the base of the filter housing. The entire filter is 90mm (3.54 inches) in length, with a maximum cross section diameter of 55mm (2.16 inches), and a mass of 24g (.85 ounces). The surface area is 26.4cm^2.

The BHF 104 has 15mm ID x 22mm OD and 22mm ID x 15mm OD male and female connectors, which allows compatibility with various compressors, ventilators, masks, and aerosol tubes.

Specifications

Tidal Volume:	150-1500ml
Flow rate resistance:	30lt/min 5mm/H20
	60lt/min 13mm/H20
	90lt/min 28mm/H20
Bacterial filtration:	>99.9999%
Viral filtration:	99.999%
Dead Space:	53ml
HME Output per ISO 9360:	37.5mg/L H2O at 500ml VT

Performance Testing

Performance was based on the following tests, which are contained in the body of the 510(k) application:

- Bacterial Filtration Efficiency (BFE)
- Viral Filtration Efficiency (VFE)
- Dead Space
- Resistance to Flow
- Heat and Moisture Exchange (HME)
- Conical Connectors

Substantial Equivalence

	DATEX-OHMEDA HMEF 500	Bacterial/Viral HME Filter (BHF 104)
510(k) #	K021265	N/A
Indications for use	The HMEF500 is a disposable single-use device indicated for patients **who** require humidification during the delivery of ventilator gases and provide filtration for reducing possible cross contamination between patient and equipment. The HMEF 500 is for use in hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators. The device can be used on adult and pediatric patients. The device is indicated for use by qualified medical personnel only.	The BHF 104 is a disposable single-use filter for patients who require humidification during the delivery of ventilator gases and provide filtration for reducing possible cross-contamination between patient and equipment. The BHF 104 is for use in hospital, ICU, anesthesia, and respiratory therapy.
Diameter	45mm	55mm
Length	74mm	90mm
BFE	99.999%	99.9999%
VFE	99.98%	99.999%
Housing Material	PP Polypropylene	K-Resin KR03 – Styrene Butadiene Block Copolymer
Filter Material	PP and Acrylic Fibers	3M Filtrete Air Media Filter – Type G
Fittings	15mm ID x 22mm OD 15mm OD x 22mm ID	15mm ID x 22mm OD 15mm OD x 22mm ID
Moisture Output	30mg H2O/L @ 500ml VT	37.5 mg H2O/L @ 500ml VT
Tidal Volume Range	120-500	150-1500
Dead Space	30ml	53ml
Weight	15g	24g
Sampling Port	Luer lock	Luer lock

None of the differences listed in the table above have any affect on safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sunset Healthcare Solutions, LLC
C/O Mr. Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Incorporated
5401 S. Cottonwood Court
Greenwood Village, Colorado 80121

SEP 13 2011

Re: K102483
Trade/Device Name: Sunset Healthcare Solutions Bacterial/Viral HME Filter (BHF 104)
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: August 19, 2011
Received: August 22, 2011

Dear Mr. Walls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102483

Device Name: Sunset Healthcare Solutions Bacterial/Viral HME Filter (BHF 104)

Indications for Use: The BHF 104 is a disposable single-use filter for patients who require humidification during the delivery of ventilator gases and provide filtration for reducing possible cross-contamination between patient and equipment. The BHF 104 is for use in hospital, ICU, anesthesia, and respiratory therapy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schutten

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 10 2 4 83